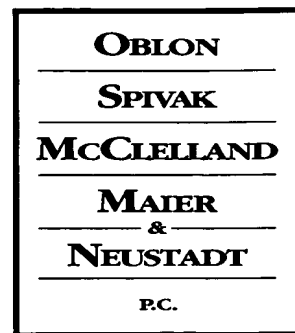




Docket No.: 208858US0PCT

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

RE: Application Serial No.: 09/831,888  
Applicants: David Andrew LEWIS, et al.  
Filing Date: July 19, 2001  
For: PRESSURISED METERED DOSE INHALERS (MDI)  
Group Art Unit: 3761  
Examiner: MITCHELL, T. K.

SIR:

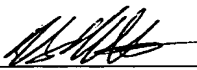
Attached hereto for filing are the following papers:

**Response to Notice of Non-Compliant Amendment  
Copy of Preliminary Amendment filed September 30, 2002**

Our check in the amount of \$0.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

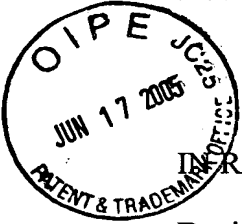
  
\_\_\_\_\_  
Vincent K. Shier, Ph.D.  
Registration No. 50,552

Customer Number

**22850**

(703) 413-3000 (phone)  
(703) 413-2220 (fax)

Docket No.: 208858US0PCT



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

David LEWIS, et al.

SERIAL NO: 09/831,888

FILED: JULY 19, 2001

FOR: PRESSURISED METERED DOSE INHALER (MDI)

:

: ART UNIT: 3743

:

: EXAMINER: MITCHELL, T. K.

RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

SIR:

In response to the Notice of Non-Compliant Amendment mailed on May 17, 2005, Applicants request withdrawal of the same on the basis that the Office has erred in the issuance of this Notice since the record is complete.

Applicants direct the Examiner's attention to the fact that the last amendment to the claims filed in this application was by way of Preliminary Amendment filed on September 30, 2002. This Preliminary Amendment contained 8 pages. Inspection of the Image File Wrapper for this application under the entries designated with the date September 30, 2002, reveal three such entries warranting note. First, page 1 of the Preliminary Amendment appears under the designation "*Amendment - After Non-Final Rejection*," pages 2-6 appear under the designation "*Claims*," and pages 7-8 appear under the designation "*Applicant Arguments or Remarks Made in an Amendment*." Of special note is that the first half of Claim 11 appears on page 1 of the Preliminary Amendment and, as such, the Examiner is referred to the section designated "*Amendment - After Non-Final Rejection*." For the


Examiner's convenience, Applicants submit herewith a copy of the Preliminary Amendment filed on September 30, 2002, as obtained from the Office's Image File Wrapper for this application.

Finally, Applicants remind the Examiner that revised 37 C.F.R. §1.121, which required the amendments to the claims to commence on a separate sheet of paper, did not become effective until July 30, 2003 (see Consolidated rules (Appendix R) appearing in the May 2004 revision of the MPEP). As stated above, the enclosed Preliminary Amendment was originally filed on September 30, 2002, 10 months before the rule change. As such, the enclosed Preliminary Amendment was timely filed (as evidenced by the OIPE date-stamp) and is in compliance with 37 C.F.R. §1.121.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



Stephen G. Baxter, Ph.D.  
Registration No. 32,884

Vincent K. Shier, Ph.D.  
Registration No. 50,552

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10-9-02  
#8/Pre  
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DOCKET NO.: 208858US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

DAVID LEWIS ET AL

:

: EXAMINER:

SERIAL NO. : 09/831,888

:

FILED: JULY 19, 2001

: GROUP ART UNIT: 3761

FOR: PRESSURISED METERED  
DOSE INHALERS (MDI)

:

PRELIMINARY AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

Prior to examination on the merits, Applicants respectfully request entry and  
consideration of the following amendments.

IN THE CLAIMS

Please amend the claims as shown on the attached marked-up copy to read as follows.

Please cancel Claims 1-10, without prejudice toward the further prosecution of these  
claims in a continuation and/or divisional application.

Please add the following new claims:

11. (New) A pressurized metered dose inhaler, said inhaler containing a solution  
comprising an active ingredient, a hydrofluorocarbon propellant, and a cosolvent, wherein

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said inhaler has an internal surface and all or part of said internal surface is a material selected from the group consisting of stainless steel and anodized aluminum.

12. (New) The pressurized metered dose inhaler of Claim 11, wherein said solution further comprises a low-volatility component.

13. (New) The pressurized metered dose inhaler of Claim 12, wherein said low-volatility component is selected from the group consisting of propylene glycol, glycerol, polyethylene glycol, and isopropyl myristate.

14. (New) The pressurized metered dose inhaler of Claim 11, wherein said active ingredient is selected from the group consisting of  $\beta$ 2 agonists, steroids, anticholinergic agents, and mixtures thereof.

15. (New) The pressurized metered dose inhaler of Claim 11, wherein said active ingredient is selected from the group consisting of  $\beta$ -adrenergic agonists, ipratropium bromide, oxitropium bromide, tiotropium bromide, flunisolide, triamcinolone acetonide, fluticasone propionate, mometasone furoate, budesonide, ciclesonide, rofleponide, and epimers thereof.

16. (New) The pressurized metered dose inhaler of Claim 11, wherein said co-solvent is ethanol.

17. (New) The pressurized metered dose inhaler of Claim 11, wherein said propellant is selected from the group consisting of HFA 227, HFA 134a, and mixtures thereof.

18. (New) The pressurized metered dose inhaler of Claim 11, wherein part or all of said internal surface is stainless steel.

19. (New) The pressurized metered dose inhaler of Claim 11, wherein part or all of said internal surface is anodized aluminum.

20. (New) The pressurized metered dose inhaler of Claim 11, wherein said solution further comprises a low-volatility component; said low-volatility component is selected from the group consisting of propylene glycol, glycerol, polyethylene glycol, and isopropyl myristate; said active ingredient is selected from the group consisting of  $\beta$ -adrenergic agonists, ipratropium bromide, oxitropium bromide, tiotropium bromide, flunisolide, triamcinolone acetonide, fluticasone propionate, mometasone furoate, budesonide, ciclesonide, rofleponide, and epimers thereof; said co-solvent is ethanol; said propellant is selected from the group consisting of HFA 227, HFA 134a, and mixtures thereof; and part or all of said internal surface is stainless steel.

B-1  
cont. p.  
21. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is ipratropium bromide.

22. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is oxitropium bromide.

23. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is tiotropium bromide.

24. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is flunisolide.

25. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is triamcinolone acetonide.

26. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is fluticasone propionate.

27. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is mometasone furoate.

28. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is budesonide.

29. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is ciclesonide.

30. (New) The pressurized metered dose inhaler of Claim 20, wherein said active ingredient is rofleponide.

31. (New) The pressurized metered dose inhaler of Claim 11, wherein said solution further comprises a low-volatility component; said low-volatility component is selected from the group consisting of propylene glycol, glycerol, polyethylene glycol, and isopropyl myristate; said active ingredient is selected from the group consisting of  $\beta$ -adrenergic agonists, ipratropium bromide, oxitropium bromide, tiotropium bromide, flunisolide, triamcinolone acetonide, fluticasone propionate, mometasone furoate, budesonide, ciclesonide, rofleponide, and epimers thereof; said co-solvent is ethanol; said propellant is selected from the group consisting of HFA 227, HFA 134a, and mixtures thereof; and part or all of said internal surface is anodized aluminum.

32. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is ipratropium bromide.

33. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is oxitropium bromide.

34. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is tiotropium bromide.

35. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is flunisolide.

36. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is triamcinolone acetonide.

37. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is fluticasone propionate.

38. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is mometasone furoate.

39. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is budesonide.

40. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is ciclesonide.

41. (New) The pressurized metered dose inhaler of Claim 31, wherein said active ingredient is rofleponide.

42. (New) The pressurized metered dose inhaler of Claim 15, wherein said active  $\beta$ -adrenergic agonist is selected from the group consisting of salbutamol, formoterol, salmeterol, and TA 2005.

43. (New) The pressurized metered dose inhaler of Claim 20, wherein said active  $\beta$ -adrenergic agonist is selected from the group consisting of salbutamol, formoterol, salmeterol, and TA 2005.

44. (New) The pressurized metered dose inhaler of Claim 31, wherein said active  $\beta$ -adrenergic agonist is selected from the group consisting of salbutamol, formoterol, salmeterol, and TA 2005.



### SUPPORT FOR THE AMENDMENTS

Applicants have canceled Claims 1-10 and added new Claims 11-41. Support for new Claims 11 and 12 can be found in Claim 1 as originally filed. Support for new Claim 13 can be found in Claim 4 as originally filed, and page 7, lines 12-15. Support for new Claim 14 can be found in Claim 2 as originally filed. Support for new Claim 15 can be found in claim 3 as originally filed, and page 8, lines 19-27. Support for new Claim 16 can be found in Claim 5 as originally filed. Support for new Claim 17 can be found in Claim 6 as originally filed. Support for new Claims 18 and 19 can be found in Claim 1 as originally filed. Support for new Claim 20 can be found in Claims 1 and 3-6 as originally filed, and page 7, lines 12-15, and page 8, lines 19-27. Support for new Claims 21-30 and 32-41 can be found in Claim 3 as originally filed. Support for new Claim 31 can be found in Claims 1 and 3-6 as originally filed, and page 7, lines 12-15, and page 8, lines 19-27. Support for Claims 42-44 can be found on page 8, lines 26-28, of the specification.

No new matter has been added. Claims 11-44 are active in this application.

REMARKS

Applicants submit that the application is ready for examination on the merits, and  
early notification of such action is earnestly solicited.

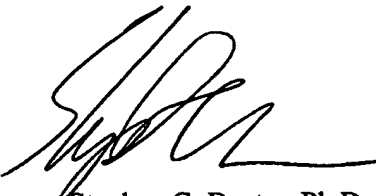
Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Norman F. Oblon  
Attorney of Record  
Registration No. 24,618



**22850**



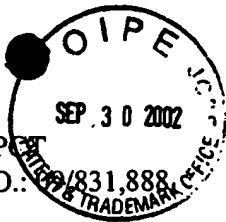
Stephen G. Baxter, Ph.D.  
Registration No. 32,884

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DOCKET NO.: 208858US0PCT

APPLICATION SERIAL NO.: 831,888



**MARKED-UP COPY OF AMENDMENT FILED HERewith**

**IN THE CLAIMS**

Please cancel Claims 1-10, without prejudice toward the further prosecution of these claims in a continuation and/or divisional application.

Please add the following new claims:

--11. (New) to 41. (New)--